K090281

MAR 4 2009

Section 5 – 510(k) Summary or 510(k) Statement

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I. General Information

Submitter:	Accutech Medical Technologies, Inc. 125 Fleming Drive Cambridge, Ontario N1T 2B8 Canada
Contact Person:	Gregory Berzak Regulatory Affairs Officer Tel: 519-620-3900, ext. 1901
Summary Preparation Date:	February 4, 2009

II. Names

Device Names:	Accutech Family of PowerFlex Laser Delivery Devices
Primary Classification Names:	Accessory for, Laser Powered Surgical Instruments

III. Predicate Devices

- Accutech EndoLite Probe (K061025)
- Cook Urological OptiLite™ Holmium Laser Fibers (K073496);
- FiberTech (FT) Fiber Optic Delivery Systems (K050738);
- Technology Delivery Systems MaxiFlex Fiberoptic Energy Delivery System (K013300)

IV. Product Description

The Accutech Family of PowerFlex Laser Delivery Devices is comprised of the following main components (by fiber optic configuration type):

Bare Fibers – No Sheaths
- Glass fiber optic with jacket
- SMA connector

Bare Fibers - With Sheaths
- Glass fiber optic with jacket
- Sheath
- SMA connector

SideFire Fibers
- Glass fiber optic with jacket with distal (patient contact) fiber tip encased in glass capillary tube
- SMA connector
- Adjustable handle (tightens on fiber to allow user to direct laser energy to desired target site)

Endoprobes/ ENT Fibers

- A glass fiber optic protected by a medical grade stainless steel needle/ cannula (patient contact) and handle at the distal end and by a plastic jacket from the proximal to distal end
- SMA connector

Additional Accessory(ies)

- Optional Radiofrequency identification (RF ID) connector for use with INTERmedic Diode Laser Family of lasers (as specified to Accutech Medical by INTERmedic for use with their laser systems)

V. Indications for Use

The Accutech Family of PowerFlex laser delivery devices (bare fibers, sidefire fibers, ENT fibers, and Endoprobes) are indicated for incision/ excision, ablation, and coagulation (hemostasis) when attached to cleared laser systems such as KTP, Nd:YAG, Argon, Diode and Ho:YAG wavelengths (488 – 2100 nm) for the indications for which the lasers have been cleared, including: general and cosmetic surgery, intraoral soft-tissue, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery.

VI. Rationale for Substantial Equivalence

The Accutech Family of PowerFlex Laser Delivery Devices shares the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Accutech Family of PowerFlex Laser Delivery Devices is substantially equivalent to the predicate devices.

VIII. Conclusion

The Accutech Family of PowerFlex Laser Delivery Devices was found to be substantially equivalent to the predicate devices.

The Accutech Family of PowerFlex Laser Delivery Devices shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 4 2009

Accutech Medical Technologies, Inc.
% A L Voss Associates
Ms. Anne Worden
3637 Bernal Avenue
Pleasanton, California 94566

Re: K090281
Trade/Device Name: Accutech Family of PowerFlex Laser Delivery Devices
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: February 4, 2009
Received: February 5, 2009

Dear Ms. Worden:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

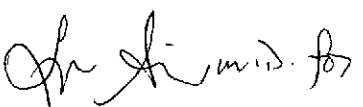
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K090281

Device Name: Accutech Family of PowerFlex Laser Delivery Devices

Indications for Use:

The Accutech Family of PowerFlex laser delivery devices (bare fibers, sidefire fibers, ENT fibers, and Endoprobes) are indicated for incision/ excision, ablation, and coagulation (hemostasis) when attached to cleared laser systems such as KTP, Nd:YAG, Argon, Diode and Ho:YAG wavelengths (488 – 2100 nm) for the indications for which the lasers have been cleared, including: general and cosmetic surgery, intraoral soft-tissue, otolaryngology, arthroscopy, gastroenterology, general surgery, dermatology & plastic surgery, neurosurgery, gynecology, urology, ophthalmology and pulmonary surgery.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

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